DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Barco NV
% Mr. Lieven De Wandel
Regulatory Affairs Officer
35 President Kennedypark
8500 Kortrijk
BELGIUM

November 12, 2014

Re: K143157
Trade/Device Name: Coronis Fusion 4MP LED
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: October 21, 2014
Received: November 3, 2014

Dear Mr. De Wandel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143157

Device Name
Coronis Fusion 4MP LED (MDCC-4230)

Indications for Use *(Describe)*
The Coronis Fusion 4MP LED (MDCC-4230) Medical Flat Panel Display System is intended to be used as a tool in displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary (in accordance with 21 CFR 807.92)

1. Company	Barco N.V. Healthcare Division 35 President Kennedypark B-8500 Kortrijk BELGIUM
2. Contact person	Lieven De Wandel Regulatory Affairs Officer
3. Date of submission	October 21, 2014
4. Device information	Trade name/model: Coronis Fusion 4MP LED (MDCC-4230) Common name: 4MP color LCD display Classification name: System, image processing, Radiological Classification code: PGY Regulation number: 892.2050
5. Predicate device	Coronis Fusion 4MP DL (MDCC-4130) cleared under 510(K) K111989
6. Device description	The Coronis Fusion 4MP LED (MDCC-4230) is a high-resolution flat panel LCD display system for reviewing medical images. It consists of an LCD display (MDCC-4230), an optional high-resolution display controller board and QA software. The display controller board is installed in a PACS workstation computer, connected to the display. The QA software helps to make and keep the displays DICOM compliant. The display uses LED backlight technology.
7. Intended Use of the Device	The Coronis Fusion 4MP LED (MDCC-4230) Medical Flat Panel Display System is intended to be used as a tool in displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.
8. Comparison of technological characteristics	

Specification	**MDCC-4130**	**MDCC-4230**
Screen technology	TFT AM LCD Dual Domain IPS Pro	TFT AM LCD Dual Domain IPS Pro
Active screen size (diagonal)	756 mm (29.8")	756 mm (29.8")
Active screen size (H x V)	641.28 x 400.8 mm (25.2 x 15.8")	641.28 x 400.8 mm (25.2 x 15.8")
Aspect ratio (H:V)	16:10	16:10
Resolution	4MP (2560 x 1600)	4MP (2560 x 1600)
Pixel pitch	0.2505 mm	0.2505 mm
Color imaging	Yes	Yes
Gray imaging	No	No

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	Viewing angle (H, V)	170°	178°
	Uniform Luminance Technology (ULT)	Yes	Yes
	Per Pixel Uniformity (PPU)	No	Yes
	Ambient Light Compensation (ALC)	Yes	Yes
	Backlight Output Stabilization (BLOS)	Yes	Yes
	I-Guard	Yes	Yes
	Maximum luminance	950 cd/m²	720 cd/m²
	DICOM calibrated luminance (ULT off)	500 cd/m²	500 cd/m²
	Contrast ratio (typical)	1100:1	1000:1
	Response time (Tr + Tf)	20 ms	20 ms
	Scanning frequency (H; V)	30-150 kHz; 15-80 Hz	30-150 kHz; 15-80 Hz
	Video input signals	DVI-D Dual Link	DVI-D Dual Link / DisplayPort 1.1
	USB ports	1 upstream (endpoint), 3 downstream	1 upstream (endpoint), 3 downstream
	USB standard	1.0	2.0
	Power requirements (nominal)	100-240V	100-240V
	Power consumption (nominal)	135W	105W
	Power save mode	Yes	Yes
	Net weight with stand	28.1 kg	21.5 kg
	Net weight w/o stand	21.6 kg	15 kg

9. Performance testing

The bench tests mentioned below were performed to validate the device characteristics that differ from the predicate device:

Modification to device	**Test performed**
LED backlight instead of CCFL	DICOM calibration and Luminance Uniformity tests
Different platform (including firmware)	Firmware tests
Additional DisplayPort video input	Firmware tests
Uniformity correction: Per pixel uniformity (vs per zone unif. on predicate device)	Luminance Uniformity tests
Other material of front filter	Impact test in IEC 60601-1 tests
Other material for sheet metal parts	Shock and Vibration tests in Environmental test report

Additional tests performed: Electrical Safety test (IEC 60601-1), EMC test (IEC 60601-1-2)

The tests showed that the device has similar or superior characteristics compared to the predicate device and did not reveal new issues of safety and performance.

Animal or clinical testing have not been performed.

10. Conclusion

The Coronis Fusion 4MP LED (MDCC-4230) was found to be substantially equivalent to

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	the predicate device, due to the following reasons: a) Device and predicate device have the same intended use b) The technological characteristics differences from the predicate device do not affect safety or effectiveness c) Bench testing showed that the device has similar or superior characteristics compared to the predicate device and did not reveal new issues of safety and performance.

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